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Message Text

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ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-09 /028 R

DRAFTED BY DHEU/FDA: JRWEIDROT;, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III

DHEW/PHS/OASH/OIH: REVANS
EA/ROC WLUNDY
----------107065 272025Z /70
P 272016Z JUL 78
FM SECSTATE WASHDC
TO AMEMBASSY TAIPEI PRIORITY

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E.O. 11652:N/A

TAGS: OGEN, EI;D, ETRD, TBIO, TW

SUBJECT: FDA ADVISORY - RECALL D-164/186-8

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED - JACOBSON'S SOLUTION CONTROL NUMBER
11219 - 29,200 VIALS.

2. PRODUCT IDENTIFICATION - JACOBSON'S SOLUTION (VITAMIN A
INJECTABLE). EACH AMPULE, VIAL AND UNIT BOX IS LABELED AND
BEARS THE DISTRIBUTORS LABEL AS FOLLOWS "FOR CONSOLIDATED
MIDLAND CORP., BREWSTER, N.Y. 10509" (CONSOLIDATED MIDLAND
IS A DIRECT CONSIGNEE OF GOTHAM LABS).

3. MANUFACTURER/RECALLING FIRM - GOTHAM PHARMACEUTICAL CO.,
1840 MCDONALD AVENUE, BROOKLYN, N.Y.

4. REASON FOR RECALL - GOTHAM PHARMACEUTICAL CO. HAS
MANUFACTURED SMALL VOLUME INJECTABLE PRODUCTS IN VIOLATION
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OF THE GOOD MANUFACTURING PRACTICE REGULATIONS. THEIR
PROCEDURES DID NOT PROVIDE ADEQUATE ASSURANCE OF STERILITY
IN NON-TERMINALLY STERILIZED PRODUCTS. CONSOLIDATED
MIDLAND HAD SOLD 29,200 VIALS OF JACOBSONS SOLUTION TO:
LIENKOO TRADING COMPANY, LTD., P.O. BOX 3484, TAIPEI,
TAIWAN.

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5. AS OF JULY 13, 1978, CONSOLIDATED MIDLAND HAD NOT ATTEMPTED TO CONTACT LIENKOO TRADING CO., LTD. EITHER PRIOR TO NOR AFTER FDA'S VISIT TO FIRM.

6. POST IS REQUESTED TO CONTACT LIENKOO TRADING COMPANY AND ADVISE THEM OF RECALL OF PRODUCT PURCHASED FROM CONSOLIDATED MIDLAND. ANY QUESTIONS LIENKOO MAY HAVE WITH RESPECT TO RECALL SHOULD BE REFERRED TO CONSOLIDATED MIDLAND CORPORATION. CHRISTOPHER

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Message Attributes

Automatic Decaptioning: X
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Current Classification: UNCLASSIFIED
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Control Number: n/a
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Draft Date: 27 jul 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Review Release Date: N/A
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Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1864553
Secure: OPEN
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TAGS: OGEN, EAID, ETRD, TBIO, TW
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